Shriners Hospitals for Children
Chicago

2211 N. Oak Park Ave.
Chicago, Illinois
60707-3392

Telephone
773.622.5400
TDD
773.385.5419
Fax
773.385.5453

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A. James Spang, MHA
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Providing pediatric orthopaedic surgery; plastic, reconstructive and maxillofacial surgery; and spinal cord injury rehabilitation since 1926.

December 1, 1999

1143 '99 DEC -7 A10:33

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville. MD 20852

RE: Docket #97N-484S

To Whom It May Concern:

I have been informed that there may be forthcoming an FDA regulation that would allow the FDA to regulate some types of allograft as medical devices. Specifically, as I understand it, this would involve allograft bone. Currently, bone banks provide bone as tissue, and the FDA regulates this in terms of its safety. However, regulations that would classify bone banks and allograft bone as devices would potentially remove from availability *tissue* which has been used for many years if the FDA would require pre-market requirements like sponsoring clinical trials and completing various regulatory documents.

Those of us who care for children and patients with spinal deformities depend greatly on bone banks to provide sufficient allograft for us to be able to achieve a solid spinal fusion in these patients. Additionally, those of us who take care of musculoskeletal tumor patients rely on allograft bone to be able to reconstruct the skeleton after tumor resection. There is abundant literature to show that these allografts are effective and safe for use in these applications. It would be a great disservice to our patients if all of a sudden the FDA requires all this new regulation and documentation that might curtail the supply of this tissue for uses that I have described above.

As a pediatric orthopaedic surgeon who has a busy practice that utilizes large amounts of bank bone, I urge you to reconsider any thought of subjecting allograft to the kind of regulatory process that medical devices are required to go through. This is an important issue for myself and my patients.

Sincerely,

John P. Lubicky, M.D., F.A.A.O.S., F.A.A.P.
Chief of Staff, Shriners Hospital for Children
Professor of Orthopaedic Surgery
Rush Medical College

Phone: 773-385-5500
Fax: 773-385-5488
e-mail: Jlubicky@AOL.com

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Chicago, Illinois
60707-3392

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